# Medical Laboratory Science Council of Nigeria

# Guideline on Sample Management

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| **Policy Statement** | Medical Laboratory Science Council of Nigeria recognizes that sample management and storage are critical to meeting the health needs of the nation. Consequently, council is committed to helping medical laboratory facilities in Nigeria to deliver quality medical laboratory service through proper sample management from pre-analytical (sample collection), analytical and post analytical stages. |

## 1. INTRODUCTION

Proper management of medical laboratory sample is critical to reliability of test results as Medical Laboratory results influence therapeutic decisions and can have significant impact on patient care and outcomes. It has become imperative to share with stakeholders certain issues relating to the handling and processing of biological specimens by providing information from international standards whilst presenting the implementation in the local context. Specific issues defined by MLSCN as major concerns on sample integrity include: prolonged contact of serum or plasma with red blood cells or tube covers, haemolysis, changes in the concentration of measurand due to evaporation, inadequate trainings, paucity of funds, inappropriate storage temperature, use of wrong anticoagulant, inappropriate handling and transport as well as prolonged storage of sample before analysis. Proper management of samples is critical to the accuracy, reliability of testing, and confidence in laboratory diagnosis.

Medical Laboratories shall establish written policies for sample management which should be reflected in the Laboratory Handbook covering all aspects of sample management components. Medical Laboratory Science Council of Nigeria as a regulatory agency therefore, has the mandate to provide a clear direction on sample management which seeks to protect our citizens and environment from possible outbreak of infectious disease and pollution.

This guideline shall apply to all Medical Laboratory facilities both public and private, that provides medical laboratory services to patients within Nigeria.

## 2. PURPOSE

This document is to serve as a guideline for sample management in laboratories, from the point of collection, processing to disposal.

## 3. ABREVIATIONS

CDC: US Centers for Disease Control and Prevention

CLIA**:** Clinical Laboratory Improvement Amendments

CLSI: Clinical and Laboratory Standards Institute

MLSCN: Medical Laboratory Science Council of Nigeria

NCDC: Nigeria Centers for Disease Control and Prevention

PPE: Personal Protective Equipment

SOP: Standard Operating Procedures

## 4. TERMS AND DEFINITIONS

### 4.1 Specimen or Primary Sample

This is discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole. Sample of biological origin intended for examination by a medical laboratory.

### 4.2 Sample

One or more parts taken from a system and intended to provide information on the system (ISO 15189:2007).

### 4.3 Patient

A person who requires medical care.**4.4 Body fluids**

Fluid contained in the three fluid compartments of the body: the plasma of the circulating blood, the interstitial fluid between the cells, and the cell fluid within the cells.

### 4.5 Primary tube

A container that provides an immediate barrier between a hazardous agent and the environment.

### 4.6 Analyte

Any substance or constituent being subjected to analysis, or which the lab conducts testing per CLIA 88 rules.

## 5. STANDARD PRECAUTIONS

The infectious agent(s) of any biological specimen remains unknown until laboratory diagnosis are carried out. It is therefore difficult to know which sample might be infectious at the time of handling and processing. Thus all patient and laboratory specimens are treated as infectious and handled according to “standard precautions.” Standard precautions are guidelines prescribing ways of avoiding contact with patients' bodily fluids through the practice of good hygiene , such as hand washing and the correct usage of appropriate PPEs, correct handling of hypodermic needles and sharp objects as well as general aseptic techniques.

Additional precautions on the other hand are used as extra measures when handling patients or specimen known or suspected to have an infectious condition, the type of prescribed measures often depend on the infection control need for the infectious agents. Specific infection control need can be found in the agent summary section of Biosafety in Microbiological and Biomedical Laboratories from the U.S. Centers for Disease Control and Prevention (HHS Publication No. (CDC) 21-1112, Revised December 2009). For additional specific precautions for preventing the laboratory acquired infections (LAI) and recommendations for the management of exposure to all infectious disease, refer to the most current edition of CLSI document M29— Protection of Laboratory Workers from Occupationally Acquired Infections.

## 6. Sample Collection

The following rules should apply:

i. Develop and use SOP
ii. Ensure patients are adequately prepared for sample collection
iii. Separate collection from testing area
iv. Ensure appropriate use of PPEs
v. Conduct Training and re-training of laboratory personnel involved in sample collection and processing
vi. Ensure proper waste management in-line with MLSCN guidelines on Waste Management
vii. Ensure provision of all materials needed for sample collection

7.2 Order of blood draw using vacutainers.

When a patient present with multiple Laboratory investigations, blood must be drawn in a specific order to avoid cross-contamination of additives between tubes.

The order described below should be considered as part of proper management of the specimen:

1. **Blood culture sample**: Blood cultures are used in microbiology. The additive it uses is a broth mixture that is intended to preserve the quality of microorganisms.
2. **Coagulation studies (Sodium Citrate tubes):** Coagulation tubes have light blue-colored stopper and a sodium citrate additive.
3. **Plain tubes (Red cover vacutainers – No Additive)**: This is commonly used for laboratory tests that require serum sample.
4. **Clot Activator tubes**: Tubes with clot activator causes blood clots and help in separating the serum by centrifugation. This process is often used in blood bank (cross-match), chemistry, immunology and serology.

5. **Serum separator tube /Gel tubes**: SST does not have any additive but a clot activator that will separate blood from the serum by centrifugation. This draw is used in chemistry, immunology and serology.
6. **Lithium Heparin (green cap vacutainer tubes)**: Tubes with green tops have lithium heparin anticoagulant and is useful for chemistry tests that require the use of plasma samples.
7. **EDTA tubes**: The EDTA anticoagulant in tubes with lavender or purple stopper helps remove calcium by forming calcium salts. This draw is often used in blood bank cross-matching and haematology.
8. **Sodium Fluoride tubes**: Tubes with gray-colored stopper contain sodium fluoride additives, which acts as an antiglycolytic agent that helps preserve glucose for up to five days.

Order of draw using Open System

1. Draw blood with needle and syringe
2. Remove needle and discard in sharps container
3. Dispense the blood into appropriate container

Procedures should be described for all testing fields in the laboratory covering samples collected in Histology/cytology, Medical microbiology, Haematology, Clinical Chemistry, Genetics, etc.

## 7. SAMPLE TRANSPORT

Samples should be transported according to MLSCN's Guidelines on safe transport of infectious/ exempt substances (ref MLSCN/2018/005),

## 8. SAMPLE RECEIVING, HANDLING AND RECORDING

The Medical Laboratory shall:

i. Ensure that all samples and requests received are checked and acknowledged receipt by the laboratory staff

ii. Develop and document criteria for acceptance and rejection of primary samples

iii. Ensure that all samples and requests are screened using the following procedures for acceptance of the request –

   a. Correctly match the two personal identifiers between the sample and the request form for the laboratory test (electronic or manual);

   b. Ensure that the appropriate sample container is used

   c. Ensure that there are no other reasons for rejection of the primary sample

iv. Ensure that all rejected requests are recorded and the authorized requestor informed

v. Ensure that all samples and requests received are recorded. The date and time of receipt of sample as well as the identity of the receiving officer, shall be recorded.

vi. Ensure that all secondary samples are adequately labelled for ease of traceability to the primary sample (when separation of sample is required)

vii. Ensure that all samples are safely stored under conditions necessary to maintain sample integrity and proper labelling.

viii. Store or Dispose left over samples in accordance with the relevant regulations (See MLSCN waste management guideline)

ix. Ensure that **Standard Precautions** are observed at all times

## 9. Processing of whole blood into Plasma / serum

Serum or plasma should be separated from red blood cells as soon as possible, a maximum limit of TWO HOURS from the time of collection is recommended. A contact time of less than two hours is recommended for Glucose, potassium, Viral load, ACTH, cortisol, catecholamines, lactic acid and homocysteine.

## 10. ANALYSIS OF SAMPLES

The Medical Laboratory shall ensure that samples are tested using validated procedures.

## 11. SAMPLE STORAGE

a) describe samples to be stored

b) determine retention time

c) determine location

d) describe proper conditions for storage

e) establish method of organizing samples

f) maintain chain of sample custody at all times

## 11. SAMPLE RETENTION

a) set policy for sample retention

b) monitor stored samples, including freeze/thaw cycles

c) maintain an organized accessible system

d) establish a schedule to review all stored samples

e) establish tracking procedures

# Recommended Sample Retention schedule

**1. Applicable to all specialties of Medical Laboratory unless otherwise specified in the specialty concerned**

| | **Record/Material** | **Retention duration** |
|---|---|---|
| 1.1 | All specimens, unless specified otherwise under the specialty concerned. | Retain specimens under appropriate storage condition for 2 days after issue of report/results |

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| | | |
| 1.2 | All records and reports known to have<br>medico-legal implications upon receipt of specimen | Indefinite |

**2. ANATOMICAL PATHOLOGY**

| | **Specimen Type** | **Retention duration** |
|---|---|---|
| 2.1 | 2.1.1 Immunofluorescence slides<br>2.1.2 All other slides including special stains and frozen sections | 2 days after issue of report<br>7 years |
| 2.2 | Blocks, including paraffin blocks from frozen section tissue | 20 years |
| 2.3 | Frozen tissue blocks for immunofluorescence studies | 3 months |
| 2.4 | 2.4.1 Unblocked tissue removed at surgery<br>2.4.2 Unblocked tissue retained at autopsy | 1 month after issue of report<br>3 months after issue of autopsy report |
| 2.5 | Autopsy<br>2.5.1 Tissue blocks<br>2.5.2 Slides | <br>20 years<br>7 years |

**3. CYTOLOGY**

| | **Specimen Type** | **Retention duration** |
|---|---|---|

| | | |
|---|---|---|
| | | |
| 3.1 | Exfoliative and Fine Needle Aspiration Cytology (FNAC)<br>3.1.1 Slides<br>3.1.2 Cell blocks | <br><br>7 years<br>20 years |
| 3.2 | Sputum, urine, cerebrospinal fluid and other body fluids | 2 days after issue of report |
| 3.3 | Specimens received in liquid based fixative | 1 month after issue of report |

## 4. HAEMATOLOGY

| | Specimen Type | Retention duration |
|---|---|---|
| 4.1 | Reported blood film (i.e. slide) | 3 years after issue of report |
| 4.2 | 4.2.1 Blood samples<br>4.2.2 Urine samples (e.g. for haemosiderin) | 2 days after test is done<br>24 hrs after test is done |
| 4.3 | Bone marrow slides | 7 years after issue of report |

## 5. CLINICAL CHEMISTRY/ CHEMICAL PATHOLOGY

| | Specimen Type | Retention duration |
|---|---|---|
| 5.1 | Samples<br>5.1.1 Serum, plasma, blood, frozen urine and other frozen body fluids<br>5.1.2 Other body fluids e.g. urine, cerebrospinal fluid, pleural fluid | <br><br>2 days after issue of report/ result<br>24 hours after test is done |

## 6. IMMUNOLOGY

| | Specimen Type | Retention duration |
|---|---|---|
| 6.1 | Samples (serum, plasma, cerebrospinal | 7 days after issue of report/result |

| | | |
|---|---|---|
| | fluid, urine, etc.) | |
| 6.2 | Frozen tissue blocks | 3 months |
| 6.3 | Immunofluorescence slides | 2 days after issue of report/result |

## 7. TRANSFUSION (BLOOD BANK)

| | **Specimen Type** | **Retention duration** |
|---|---|---|
| 7.1 | Samples of materials examined | 7 days after test is done |
| 7.2 | Laboratory records of blood donations and administration of blood and blood products | 20 years |

## 8.0 MEDICAL MICROBIOLOGY

| | **Specimen Type** | **Retention duration** |
|---|---|---|
| 8.1. | Specimens for culture & sensitivity | |
| | 8.1.1 All specimens except urine & blood | 2 days after issue of report/result |
| | 8.1.2 Urine | Discard after issue of report/result |
| | 8.1.3 Blood (including fungal culture) | Negative - Discard after issue of report/result<br>Positive - 7 days after issue of report/result |

| | | |
|---|---|---|
| 8.2 | Serum/plasma for serology | Negative - Discard after issue of report/result<br>Positive - 7 days after issue of report/result |
| 8.3 | Slides<br>8.3.1 Wet preparation<br>8.3.2 Stained/ Immunofluorescence slides | Discard after issue of report/result<br>Negative- Discard after issue of report/result<br>Positive- 2 days after issue of report/ Result |

**9.**
**GENETICS**

| | **Record/Material** | **Retention duration** |
|---|---|---|
| 9.1 | Microscopic slides<br>9.1.1 Chromosome metaphase slides<br>9.1.2 Other slides | Fluorescence-stained slides - 3 months.<br>Standard stained slides -18 months.<br>7 years |
| 9.2 | Fixed chromosome preparation (blood & bone marrow) in suspension | 6 months |
| 9.3 | Tissue cultures | 6 months |
| 9.4 | Plasma, serum and urine for testing (other than DNA) for biochemical genetics | 3 months |

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| 9.5 | DNA extracts for molecular Genetics | 1 month after analysis. If part of a study, retain at least I month after study is completed. |

## 12. SAMPLE DISPOSAL

The laboratory is responsible for ensuring safe handling and disposal of all laboratory waste in line with MLSCN guideline on waste management.

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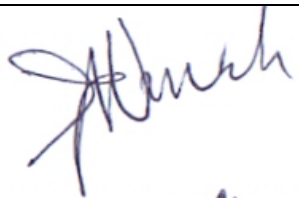
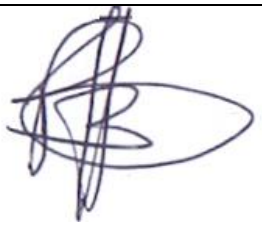
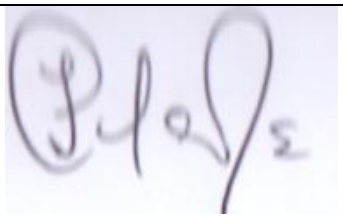
| 4 | NWOKAH, Easter G. | Rivers State University, Port Harcourt |  |
| 5 | BARDE, Joshua B. | NEQAL Laboratory/ Medical Laboratory Science Council of Nigeria |  |
| 6 | ADEOYE, Felix (Col.) | HIFASS |  |
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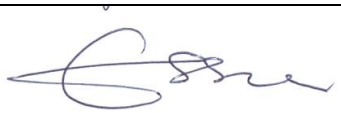
| 10 | ESSIEN, Victor | Medical Laboratory Science Council of Nigeria |  |
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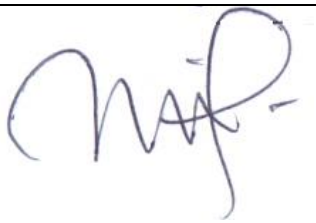
| 12 | IFEANYI, CASMIR I. C. (Dr.) | University of Abuja |  |
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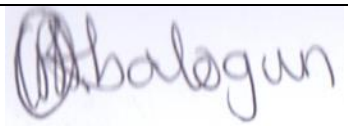
| 14 | BALAGUN. Oyebimpe | Institute of Human Virology, Nigerian |  |
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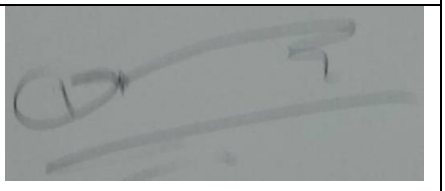
| 16 | AKINWALE, Abayomi Air Cdre (Rtd.) | USDOD Nigeria |  |

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